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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/054,619 | 01/22/2002 | Richard J. Melker | UF-270 | 5786 |
| 23557 | 7590 | 05/10/2005 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | NATNITHITHADHA, NAVIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,619

Applicant(s)

MELKER ET AL.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-32, 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 33-37 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Examiner's Comments

1. Claims 3-5, 15-17, 28-34, 38, and 40 were amended.
2. Claims 2-40 are pending.

Response to Arguments

3. Applicant's arguments, see page 8, filed September 13, 2004, with respect to claim 38 have been fully considered and are persuasive. The objection of claim 38 has been withdrawn.
4. Applicant's arguments with respect to claims 2-40 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 33, 34, and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Risby et al, US 6,248,078 B1.

As to claims 33, 34, and 40, Risby teaches a method for monitoring volatile organic molecules associated with disorders (endogenous compounds) (see figs. 1B

and 1C), comprising: collecting respiratory gas (sampling expired breath) (see col. 16, lines 46-52); analyzing the respiratory gas for volatile organic molecules (see col. 16, lines 55-60); and calculating the concentration of the volatile organic molecules (see col. 16, lines 55-60). Risby's method is able to detect the following compounds: hydrocarbons organic compounds, ammonia, along with other molecules in a human breath sample (see col. 11, lines 41-50).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of White et al, US 5,003,985 A.

In regards to claims 35 and 36, Jewett teaches anesthetic delivery system (see fig. 6 and col. 9, line 67 to col. 10, line 27) comprising: an anesthetic syringe pump vaporizer (anesthetic supply) having an anesthetic control; an anesthetic detector (breath analyzer or collector/sensor) for analyzing the expired anesthetic concentration and provides a signal; and a microprocessor (system controller or processor). Jewett does not explicitly teach the anesthetic detector analyzes the patient's breath for concentration of at least one substance indicative of the anesthetic agent concentration in the patient's bloodstream. However, White teaches a respiratory analyzer for determining and displaying the expired concentration of volatile anesthetic gases, which provide relative estimates of gas concentration in the blood (see col. 1, lines 32-39). It

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would be obvious for one of ordinary skill in the art at the time the invention was made to use the respiratory analyzer of White in combination with Jewett's anesthetic system because White suggests the respiratory analyzer "can be used as a feed-back signal for a closed anesthesia servo controller", such as Jewett's (see White, col. 1, lines 36-39). Furthermore, this provides a more effective means of delivery anesthesia.

7. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of White et al, US 5,003,985 A as applied to claim 36 above, and further in view of Lewis et al, US 6,244,096 B1.

As to claim 37, White does not explicitly teach the respiratory waveform transducer 12 is selected from semiconductor gas sensor technology, conductive polymer gas sensor technology, or surface acoustic wave (SAW) gas sensor technology. However, these are well known types of sensors for detecting respiratory compounds. Lewis teaches SAW sensors, conductive polymer gas sensors, and semiconductor sensors as alternative sensors for determining the concentration of respiratory compounds (see col. 7, lines 8-27). It would be obvious for one of ordinary skill in the art at the time the invention was made to use the respiratory sensor of Lewis in combination with the teachings of Jewett and White because Lewis suggests by using the respiratory sensor, "it is possible to detect and quantitate the concentration of volatile anesthetics" (see Lewis, col. 13, lines 7-10). Furthermore, this provides a more effective means of determining the concentration of an anesthetic.

Allowable Subject Matter

8. Claims 2-32, 38, and 39 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter:

As to claims 2-32, the prior art of record does not teach a method for determining the blood level concentration of an agent based on concentration of the agent in a sample of expired breath, wherein the agent is either a anesthetic, analgesic, muscle relaxant, sedative, or anxiolytic.

As to claim 38, the prior art of record does not teach an apparatus for administering intravenous anesthesia, comprising the combination of an intravenous delivery means and a breath analyzer for analyzing the patient's breath for concentration of the intravenous anesthetic agent.

As to claim 39, the prior art of record does not teach a method for monitoring perflubron levels in an anemic patient comprising: calculating the blood concentration of perflubron based on the concentration of perflubron in a sample of a patient's breath.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha
Patent Examiner
GAU 3736
05 May 2005